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| 10/723,716  | 11/26/2003  | Prathyusha K. Salla  | 132958-2<br>(GEMS:0262/YOD) | 9778             |
| 68174 7590 072902910<br>GE HEALTHCARE<br>c/o FLETCHER YODER, PC |             |                      | EXAMINER                    |                  |
|   |             |                      | WEATHERBY, ELLSWORTH        |                  |
| P.O. BOX 692289<br>HOUSTON, TX 77269-2289                       |             |                      | ART UNIT                    | PAPER NUMBER     |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

# Application No. Applicant(s) 10/723,716 SALLA ET AL. Office Action Summary Examiner Art Unit ELLSWORTH WEATHERBY 3768 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 04/28/2010. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 1-40 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 1-25 and 28-40 is/are rejected. 7) Claim(s) 26 and 27 is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Paper No(s)/Mail Date 01/15/2010.

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

Attachment(s)

Interview Summary (PTO-413)
 Paper No(s)/Mail Date.

Notice of Informal Patent Application
 Other: NPL1, NPL2, NPL3, NPL4, NPL5.

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#### DETAILED ACTION

## Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Omum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-25 and 28-40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-32 of copending Application No. 10/723894. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 1-32 of the co-pending application recite all the limitations of the present invention. Because both claim identical means for providing image data representative of multiple organ motion profiles, the present application's use of prospective gating does not distinguish it from the co-pending application's retrospective gating. Here, the use of retrospective gating

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and prospective gating are both well known in the art, as well as, interchangeable in both systems that acquire the same motion data.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

3. Claims 1-25 and 28-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,756,565. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-10 recite all the limitations of the present application including, including identical means for providing image data representative of multiple organ motion profiles and using the motion data to provide prospective gating and control of an imager.

## Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 8-14, 20-24, 31-36, 38-40 are rejected under 35 U.S.C. 102(b) as being anticipated by Huesman et al. (Preliminary studies of cardiac motion in positron emission tomography. Report LBNL-41433, Lawrence Berkeley National Laboratory. March 29, 2001).

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6. Huesman et al. (hereinafter Huesman) discloses an imaging system, which must inherently contain a computer program, and a method for imaging the heart with means and steps for double-gating the image data for both respiratory and cardiac motion correction (Abstract). Huesman discloses means and steps for acquiring motion data for the lungs and the heart using both an EKG and a pneumatic bellows apparatus (pg. 6, par.1), which constitute an electrical sensor with measurement system, and a non-electrical sensor with measurement system, and a non-electrical sensor with measurement system, respectively, as claimed in the instant application. Huesman extracts two prospective gating points, end inspiration and end expiration, and two retrospective gating points, end diastole and end-systole (Fig. 7). Huesman also discloses means and steps for acquiring image data of the heart and subsequently processing a portion of the image data to compensate for motion artifacts, including means and steps for reconstructing and displaying the image (pg. 9, par. 1; Fig. 7).

### Claim Rejections - 35 USC § 103

- The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Claims 1-25 and 28-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yuan et al. ("Cardiac-respiratory gating method for magnetic resonance imaging of the heart", Magnetic Resonance in Medicine 43: 314-318, 2000)

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in view of Felbinger et al (Methods and Reproducibility of Cardiac/Respiratory Double-Triggered H-MR Spectroscopy of the Human Heart) or alternatively Struber et al. (Submillimeter Three-dimensional Coronary MR Angiography with Real-time Navigator Correction: Comparison of Navigator Locations) or alternatively Manke et al. (Novel Prospective Respiratory Motion Correction Approach for Free-Breathing Coronary MR Angiography Using a Patient-Adapted Affine Motion Model).

9. Yuan et al. (hereinafter Yuan) teaches a method for imaging an organ with an imager (abstract), comprising the steps of: acquiring a set of motion data for two or more organs from at least one or two of one or more types of electrical sensors (pg. 314, Methods-Device: e.g. multiple ECG leads) or one or more types of non-electrical sensors, e.g. bellows (or displacement sensor), which is activated with a set of positional data acquired by one or more positional sensors (pg. 314, Introduction; pg. 315, Methods-Device); processing the set of motion data to extract two or more prospective gating points for an organ of interest (pg. 314. Introduction; pg. 314. Methods); and acquiring a set of image data representative of the organ of interest using the two or more prospective gating points (pg. 314, Introduction; pg. 314, Methods-Device). Yuan also teaches reconstructing the set of image data to generate a set of reconstructed data and generating an image from the set of reconstructed data (pg. 314, Introduction; e.g. k-space gradient-echo seguence allowed...cardiac images to be acquired). Yuan further teaches that wherein generating the image comprises fusing a set of image data representative of structure with at least one of a set of image data representative of motion or a set of image data representative of electrical activity (pg.

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317, Analysis; pg. 317, Discussion). Yuan also teaches that the set of motion data is at least partially acquired from a set of pre-acquisition image data (pg. 315, Analysis). Yuan further teaches an operator workstation configured to communicate with the system control circuitry and to receive the processed plurality of signals from the data processing circuitry (pg. 314, Introduction; pg. 315, Device).

- 10. Yuan teaches all the limitations of the claimed invention except for expressly teaching validating the set of motion data using another set of motion data derived from a dataset acquired using an imager. Yuan also does not expressly teach using an electrical sensor to track the second organ. Yuan also does not expressly teach measuring non-electrical activity indicative of the motion of two or more organs via one or more non-electrical sensors. Yuan also does not expressly teach fusing image data representative of motion. Yuan also does not expressly teach determining one or more motion compensation factors. Yuan also does not expressly teach the use of preacquisition image data.
- 11. In a related field of endeavor, Felbinger et al. teaches methods and reproducibility of cardiac/respiratory double-triggered imaging of the heart for improving intra- or intersubject reproducibility (Abstract; Figs. 1-5; Table 1). Felbinger goes on, teaching three methods (i.e. Method A-C), where method B comprises ECG triggering based on alternative means for respiration gating than those set forth by Yuan (pg. 903-905, Materials and Methods, Triggering methods; Figure 1). Felbinger discloses that Methods B-C produced superior results than Method A (pg. 905, Results). However, Felbinger discloses that method A could be improved by combination with a feedback

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mechanism based on method C or navigator scans (pg. 907, Discussion, par. 3, last sentence; pg. 908, Discussion, par. 6). Here, the Examiner notes that navigator scans are well known in field of endeavor as means for triggering using an MR scan.

- 12. Alternatively, Struber teaches submillimeter three-dimensional Coronary MR angiography with real-time navigator correction (Abstract; Figs. 1-6). Struber goes on, teaching that the highly complex motion pattern of the heart results is severe image degradation (pg. 579; Introduction). Struber suggests that navigators with gating and real-time motion correction result in improved imaging and suggests using a model that incorporates the relationship between diaphragmatic motion and coronary displacement may be used for real-time motion correction (pg. 579; Introduction). Here, the examiner notes that this may be interpreted as validating ECG data with MR navigation data because the navigation data enables the system or method to reject potentially poor image data (pg. 581, Navigator technique; pg. 582, Protocol; Fig. 3). Struber teaches that the use of navigator data offers excellent means to suppress respiratory motion (pg. 583, Results; pg. 584, Discussion; pg. 585, 3<sup>rd</sup> column).
- 13. Alternatively, Manke et al. (hereinafter Manke) teaches novel prospective respiratory motion correction approach for free-breathing coronary MR angiography using a patient-adapted Affine motion model (Abstract; Figs. 1-7). Here, Manke teaches that in cardiac imaging motion of the beating heart and breathing causes substantial motion in the cardiac region, where correction is not limited to translation and rotational motion (pg. 122, Introduction). Thus, Manke suggests a plurality of prospective gating points where, due to respiration motion detected by a navigator pulse, a calibration may

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applied to the plurality of prospective gating points to account for irregular or patient to patient breathing patterns as determined from pre-acquisition scan data (pg. 122; Introduction). Manke also suggests supplementing or replacing the navigators with vector ECG (pg. 130, Model Calibration Approach).

14. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the dual gating of Yuan with the multiple gatings and navigator scans of Felbinger or Struber or Manke. The motivation to modify would have been to improve the motion artifact reduction using known gating or correction mean, as is well known in the art.

### Allowable Subject Matter

15. Claims 26-27 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

# Response to Arguments

- Applicant's arguments with respect to claims 1-40 have been considered but are moot in view of the new ground(s) of rejection.
- 17. Regarding Applicant's preliminary remarks, the Examiner agrees and confirms that to date, applicant's have not filed an RCE during the prosecution of the instant application. The Examiner acknowledges that Applicant's have not filed an RCE during the prosecution of the instant application.

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18. Applicant goes on, requesting that the Examiner hold the obviousness-type double patenting rejection in abeyance until the present or copending claims are indicated as allowable. The Examiner agrees.

- 19. Regarding Applicant's alleged deficiencies of the Yuan Reference, the Examiner will address these as follows:
- 20. Applicant alleges that the Yuan reference fails to disclose the validation of the sensor-acquired set of motion data using another set of motion data derived from a dataset acquired via an imager. Here, the Examiner notes that this newly amended limitation prompted a new grounds of rejection, as addressed above. The Examiner also notes with regard to the above grounds of rejection that the EKG, bellows, or navigator pulse sequences were known at the time to be utilized in addition or as a replacement to each other, and therefore the interchangeability of the variety of gating means including EKG, bellows, or navigator pulses would be obvious to one of ordinary skill in the art at the time of the invention.
- 21. Applicant further alleges that the Yuan reference fails to disclose one or more motion compensation factors, fusing image data, and that motion data is at least partially pre-acquisition image data. With regard to Applicant's allegation's that fusing image data includes, for example, to visually conveying depolarization states, the Examiner notes that this visual conveyance is not required by the claim language. However, the examiner notes that the new grounds of rejection addresses each of the alleged deficiencies.

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#### Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EW/

/Long V Le/ Supervisory Patent Examiner, Art Unit 3768